Percutaneous Hemodynamic Support (Impella) in Patients with Advanced Heart Failure and/or Cardiogenic Shock Not Eligible to PROTECT II Trial

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Abstract

PROTECT I and II trials have tested the efficacy of Impella in patents with high-risk percutaneous coronary intervention (PCI). However, patients with severe hemodynamic instability such as cardiac arrest, ST-segment elevated myocardial infarction (STEMI), or cardiogenic shock were excluded. The objective was to investigate the efficacy of Impella in sicker patient population who were not included in PROTECT trials. These patients merit high-risk PCI who had cardiogenic shock and unstable or decompensated heart failure (HF). From December 2010 to March 2012, 10 consecutive patients with extremely high surgical risk and hemodynamic instability underwent urgent PCI with Impella 2.5 support (Abiomed Inc., Danvers, MA). These patients were presented with advance HF and/or cardiogenic shock. Among the 10 included patients, 3 patients were with cardiac arrest and 1 patient was with acute myocardial infarction. All patients had successful Impella implantation and remained hemodynamically stable during high-risk PCI. Among the 10 patients 2 patients (20%) died within 1 month and 1 patient developed limb ischemia. In high-risk population nonrandomizable to PROTECT trials with advance HF/cardiogenic shock, Impella could be an important tool for hemodynamic support to PCI or could be a bridge to left ventricle assist device to achieve good recovery. Larger studies need to be conducted on this high-risk population.

Keywords
- left ventricle assisting device
- heart failure
- percutaneous coronary intervention
- cardiogenic shock

Impella 2.5 system (Abiomed Inc., Danvers, MA) is an invasive left ventricular assist device (LVAD) that can provide hemodynamic support in patients with decompensated heart failure (HF) with poor left ventricular (LV) function undergoing high-risk percutaneous coronary intervention (PCI).[1–3] Both, PROTECT I[4] and PROTECT II trials[5] were designed to evaluate the safety, feasibility, and efficacy of the prophylactic Impella 2.5 system in patients undergoing nonemergent high-risk PCI. Results from these two and some other trials[6] showed that Impella 2.5 system is safe and can provide better hemodynamic support when compared with intra-aortic balloon pump (IABP). However, in these studies, patients with ST-segment elevation myocardial infarction (STEMI), preprocedure cardiac arrest, and cardiogenic shock were excluded.

Patients with STEMI, postarrest with cardiogenic shock or advanced decompensated HF were associated with very poor prognosis and high mortality. Early revascularization of target vessel with the support of inotropes, IABP, and LVAD can ensure hemodynamic stabilization and good recovery of

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left ventricle systolic function. Therefore, the authors sought to investigate the safety and efficacy of Impella support in sicker group of patients who are not included in PROTECT I and II trials.

Materials and Methods

Study Population

From December 2010 to March 2012, 10 consecutive patients with advanced HF, cardiogenic shock or postcardiac arrest who underwent Impella insertion as a mechanical support for urgent revascularization were included in this study. Patients who did not meet these criteria were excluded from the study. Patients clinical data were included in ►**Tables 1** and **2**. Out of 10 patients, 3 patients were presented with postcardiac arrest due to mechanical failure before PCI, 1 patient with STEMI, 6 patients with nonST-segment elevation myocardial infarction (NSTEMI) and advanced HF.

Impella System

The Impella 2.5 device is a miniaturized 12-Fr rotary blood pump that is placed across the aortic valve. The device aspirates blood from the LV cavity which is then expelled into the ascending aorta. Under clinical conditions, the pump provides up to 2.5 L/min at its maximal rotation speed of 51,000 rpm.

Procedure

The device was inserted percutaneously through a 13-Fr femoral sheath and was mounted on a 9-Fr pigtail catheter, allowing it to be easily placed across the aortic valve. The Impella device was left in place for up to 5 days. The Impella 2.5 catheter was connected distally to a portable mobile console that displays invasive pressure with actual revolutions of the pump per minute, thus guiding the correct positioning and functioning of the device. After insertion of a 13-Fr femoral arterial sheath, the Impella 2.5 system was advanced retrogradely across the aortic valve using a monorail technique and positioned in the mid-LV cavity. All patients were anticoagulated with unfractionated heparin before pump insertion to achieve an activated clotting time of 250 second.

Circulatory support was initiated before PCI with a target flow of 2.5 L/min. PCI was then performed using conventional equipment and techniques. All patients were pretreated with aspirin 325 mg and plavix 600 mg before intervention. The use of glycoprotein receptor inhibitors and timing of device removal was left at the discretion of operator. For patients

Table 1 Clinical characters and outcomes for the patients with advanced heart failure and/or cardiogenic shock underwent Impella implantation

Particulars	$N = 10$
Age, y, mean ± SD	69.7 ± 9
Gender, male, *n* (%)	6 (60)
Presentation, *n* (%)	
STEMI, *n* (%)	1 (10)
NSTEMI, *n* (%)	6 (60)
Cardiac arrest post–CPR, *n* (%)	3 (30)
LVEF, %, mean ± SD (range)	14.7 ± 9.8 (5–30%)
EuroScore, mean ± SD (range)	40 ± 12.9 (29–65)
Hemodynamic parameters	
PASP, mm Hg, mean ± SD (range)	64.5 ± 9.7 (50–79)
Cardiac index, L/(min × m^2), mean (range)	2.1 (1.3–2.6)
PCWP, mm Hg, mean ± SD (range)	31 ± 7.7(13–40)
Duration of Impella support, range	2 h–8 d
Successful PCI, mean (%)	10 (100)
Complications	
Limb ischemia requiring amputation, mean (%)	1 (10)
Anemia requiring transfusion, mean (%)	2 (20)
Outcome	
Good recovery, mean (%)	8 (80)
Bridge to LVAD, mean (%)	1 (10)
Death within 30 days, mean (%)	2 (20)

Abbreviations: LVAD, left ventricle assisting device; N, number of patients; NSTEMI, non-ST elevated myocardial infarction; PASP, pulmonary artery systolic pressure; PCI, percutaneous coronary intervention; PCWP, pulmonary capillary wedge pressure; SD, standard deviation; STEMI, ST elevated myocardial infarction; y, year.

Table 2 Case series of patients with advanced heart failure or cardiogenic shock underwent Impella implantation

Patient	Sex	Age, y	Duration of Impella, h	Cause	Target vessel	EuroScore	AKI	Complication	Outcome	EF, %	PCWP, mm Hg	PA, mm Hg
1	M	75	2	NSTEMI	LAD, RCA	29	None	None	Good	5–10	40	60/21
2	M	71	96	Cardiac arrest	LIMA	32	Yes	HIT	Dead	25	34	59/28
3	F	71	1.5	Cardiac arrest STEMI	LAD	45	Yes	None	Good	30	33	55/23
4	F	61	3	NSTEMI	LAD, RCA	30	Yes	None	Good	15	30	61/33
5	F	76	16	Cardiac arrest	LAD	46	None	None	Good	20	29	53/21
6	F	61	24	STEMI	LAD, RCA	30	None	None	Good	25	35	62/35
7	M	53	196	NSTEMI	LM, LCX	50	None	Leg ischemia	Good	5	13	68/38
8	M	69	24	NSTEMI	LCX	65	None	None	Good	5–10	39	78/29
9	M	77	96	NSTEMI	LCX, LAD	40	Yes	None	Good	5–10	27	50/31
10	M	83	72	NSTEMI	LCX, RCA, LAD	60	Yes	None	Dead	20	27	55/25

Abbreviations: AKI, acute kidney injury; EF, ejection fraction; HIT, heparin induced thrombocytopenia; LAD, left anterior descending artery; LCX, left circumflex; LIMA, left internal mammary artery; LM, left main; LVAD, left ventricle assisting device; NSTEMI, non-ST elevated myocardial infarction ; PA, pulmonary artery pressure; PCI, percutaneous coronary intervention; PCWP, pulmonary capillary wedge pressure; RCA, right coronary artery; STEMI, ST elevated myocardial infarction.

who were hemodynamically stable during PCI, weaning was commenced in the cardiac catheterization laboratory by decreasing the pump performance level in 2 steps in intervals of 2–10 minutes. Once the performance level was reduced to level P2 (range: P1 to P9; P9 = maximum flow rate) for 10 minutes without hemodynamic instability, the Impella pump was pulled back into the aorta and explanted. In patients where weaning was unable to be achieved, the Impella 2.5 remained implanted to obtain hemodynamic stability for hours or even days after insertion. Hemostasis was obtained by two preclosed proglide suture devices or by manual compression.

Study Procedure, Data Collection, and Statistical Analysis

Patient's data was collected retrospectively from the medical records. All causes of morbidity and mechanical failures were recorded. Acute renal failure was defined as urine output less than 30 mL/h. Mortality was recorded during hospitalization at 1 month and up to 1 year after implantation. Continuous variables were presented as mean and standard deviation.

Hemodynamic measurements were recorded before Impella support. A Swan-Ganz catheter was placed either from internal jugular or right/left femoral vein approach and invasive monitoring was performed. Cardiac output, wedge pressure, pulmonary artery (PA) pressure were measured and recorded. Serial blood sampling was obtained before and after Impella support for cardiac enzymes, hemoglobin, renal function, and electrolytes. The cardiopulmonary resuscitation (CPR) time was from 5 to 22 minutes.

Results

Clinical Characteristics

Clinical characteristics are presented in ►**Tables 1** and **2**. Mean age was 68.2 years. Three patients had acute-on-chronic renal failure from poor renal perfusion.

Baseline hemodynamic data before the PCI showed that most patients had very low ejection fraction (mean 14.7% and range 5–30%), high wedge pressure (mean 31 mm Hg and range 13–40 mm Hg), low cardiac index (CI) [mean 2.1 L/(min × m^2), range 1.3–2.6 L (min × m^2)], and high mean PA pressure (mean 64.5 mm Hg and range 50–79 mm Hg). This indicated decompensated HF.

Procedure

PCI was successfully performed in all patients and hemodynamic data remained stable during PCI. A total of 90% of the lesions were in left anterior–descending artery (LAD) or in left main territory. One patient was performed with LAD and first diagonal bifurcation stenting.

The pump was inserted successfully in all patients through left or right femoral approach. The Impella 2.5 worked properly in all patients during the procedure. In 1 patient, after 2 days of its implantation, the Impella device malfunctioned due to constant high-purge pressure. Then, a new Impella 2.5 device was exchanged.

Complications and Death

In this study, two patients died during hospitalization. One patient died because of HF 1 month after implantation. The patient was bridged to LVAD and died while waiting for cardiac transplantation. The other patient died from cardiogenic shock, 3 days post three-vessel PCI which was supported by Impella.

One patient developed left leg ischemia 3 days after Impella placement. The patient required endovascular treatment and left leg below knee amputation. Two patients had anemia, one was suspected to be heparin induced and the other was hemolytic anemia. Both patients were given transfusion and recovered.

Discussion

The experience at this single center showed that the use of Impella in support of high-risk urgent PCI is beneficial in patients with advanced HF, cardiogenic shock or postcardiac arrest that can occasionally be lifesaving and associated with relatively low mortality. In most of the cases, right heart study was performed before Impella implantation. The hemodynamic data from Swan-Ganz before PCI showed that most patients had very high Wedge pressure, high LVEDP, high-PA pressure and low CI. This indicated that these patients had preexisting advanced HF or profound cardiogenic shock. These patients were unlikely to complete PCI without left ventricle assistance support.

The safety and efficacy of Impella in support of PCI had been shown from PROTECT trials and other trials.[1,2,14] The PROTECT II trial concluded that patients who underwent more extensive revascularization had significantly better outcomes at 90 days with Impella support compared with those supported with IABP. USpella registry[7] confirmed the use of Impella 2.5 in a real-world multicenter setting was safe and provided sufficient hemodynamic support to facilitate high-risk single or multivessel PCI. Moreover, USpella registry data showed a very low 30-day major adverse cardiac events (MACE) rate of 8.2% and revascularization rate of only 0.9% ($n = 2$). This showed that Impella enables a more complete revascularization resulting in favorable short and midterm angiographic, procedural and clinical outcomes. However, in these studies patients were undergoing selective nonurgent PCI. In addition, patients with advanced decompensated HF, STEMI and postcardiac arrest were not explored. The patients included in this study were sicker and had preexisting hemodynamic instability which merit urgent intervention with hemodynamic support.

Hemodynamic benefit of Impella lies in its ability to continuously aspirate the blood from the LV cavity. As a result of LV unloading overall cardiac output can be improved, end-diastolic pressure and end-diastolic volume can be reduced resulting in improved organ perfusion.[8–10] In patients with advanced HF, quick restoration of coronary flow can contribute to the improvement of cardiac function. However, because of the high end-diastolic pressure, administration of large volume of contrast and temporarily blocking the coronary flow during the procedure can lead to hemodynamic collapse. The Impella pump also has a favorable effect on coronary flow by increasing the mean distal coronary pressure and coronary flow reserve.[11,12] These effects are more significant in comparison with IABP insertion. The Impella recover LP 2.5 system (Abiomed Inc., Danvers, MA) used along with the balloon pump for hemodynamic support resulted in enhanced circulatory support and dramatic improvement of patient's cardiac arrest.[13] The effect was comparable with other LVADs such as TandemHeart (Cardiac Assist Inc., Pittsburgh, PA)[14] or extracorporeal membrane oxygenation[15] in supporting high-risk PCI and cardiogenic shock.

The application of Impella in STEMI and cardiac arrest due to mechanical failure was explored in this study. A study by Engstrom et al showed that cardiogenic shock with STEMI benefited from Impella 5.0.[16] Lam et al reported that microcirculation can be improved in STEMI patients treated with Impella.[17] Compared with other LVADs such as percutaneous cardiopulmonary support system and TandemHeart, Impella is relatively easier to insert and provides similar hemodynamic support. This could be extremely important for cardiac arrest patients whose circulation needs to be quickly restored to provide enough circulation to brain.

Impella device has been successfully shown as a bridge to heart transplantation[18,19] or long-term ventricular assistance device.[20] In this study, one patient had Impella insertion as a bridge to left ventricle assistance support. All the devices were successfully placed. The more severe complications were leg ischemia in one patient with slow peripheral flow due to cardiogenic shock that required amputation and anemia due to hemolysis. These complications occurred because of prolonged stay of Impella.

Conclusion

This study showed that in high-risk population which is nonrandomizable to PROTECT II trial with advance HF/cardiogenic shock, Impella could be used as an important tool for hemodynamic support to PCI or bridge to LVAD to achieve good recovery. However, these encouraging findings must be confirmed by larger studies, longer assist times and in more homogeneous patient population.

Disclosure

There are no financial or other relations that could lead to a conflict of interests.

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